# **DRAFT PERFORMANCE WORK STATEMENT (PWS)**

# 5. EQUIPMENT REQUIREMENTS

## • Bedside Monitor General Requirements:

- Must be compatible with existing Philips Multi-Measurement Module (MMS), Flexible Module Server (FMS), and End Tidal CO2 (EtCO2) modules without additional cables. Purchase of additional or replacement MMS and/or FMS will be required based on existing inventory age and condition. Newly purchased MMS, FMS, EtO2 modules, or equivalent must be compatible and interchangeable with existing inventory.
- Must be capable of transferring patient data between the MMS and monitors for ease of patient transport without the loss of any data
- Adjustable screen layouts
- o Previous screen function to view most recently used screens
- o Capable of displaying all patient beds in a networked unit
- Choice of input options to include but not be limited to resistive touchscreen, trackball, mouse, keyboard, remote control
- o Primary mode of operation must not be a trim knob
- o Must provide a built-in help menu for on-screen operating help
- o Must be compatible with an MMS extension if additional parameters are required
- Must provide at least 3 alarm categorizations by priority; a separate or fourth category will be reserved for technical alarms
- Must be compatible with Picis/Optum PACU and OR Manager applications for existing Anesthesia Record Keeping (ARK), and Clinicomp Essentris application for Clinical Information System (CIS)
- o Must have a 1-year warranty period
- Must meet IEC 60601-1:1988, EN60601-1:1990, UL 60601-1:2003, CAN/CSA C22.2#601.1-M90, IEC 60601-1-1:2000, and be compliant with Medical Device Directive 93/42/EEC
- o Must be compatible with GCX brand mounts
- o Must utilize Nellcor SpO2, the facility standard
- MMS must provide measurement data for at least EGC/arrhythmia, respiration, oxygen saturation (SpO2), noninvasive blood pressure (NBP), and invasive blood pressure or temperature
- All monitors must provide EtCO2 monitoring
- o Must network to a central viewing station unless otherwise specified by the COR

# • Transport Monitors:

- o Must meet all bedside monitor general requirements
- o Must have a color LCD display of at least 12"
- o Must be all-in-one display and processor; must not require an additional screen
- o Must be capable of displaying at least 4 waveforms simultaneously

- Must be configured for use in ICU settings and as a transport monitor
- o Must be capable of operating using battery power for at least 3 hours
- o Must have an integrated recorder, bed hanger mount, and battery
- Must allow for installation of additional I/O boards as needed by the facility
- Must use rechargeable lithium ion batteries, which must charge in no more than 5.5 hours when the monitor is in use or no more than 3.5 hours when the monitor is switched off

# • OR/Anesthesia Monitoring:

- Must meet all bedside monitor general requirements
- Must be safe for use with Datex-Ohmeda Avance anesthesia machines
- o Must be capable of displaying at least 12 waveforms simultaneously
- Must be configured for use in the OR
- Must include at least 8 slot FMS rack with MMS mount
- o Must utilize an independent display; monitor shall not be all-in-one
- o Must have an LCD display of at least 19"
- Must be compatible with the Philips X2 or equivalent. Total cost will dictate procurement of the X2 or utilization of MMS. The X2 must provide the same functionality as the MMS, at a minimum, to include ECG, respiration, SpO2, CO2, NBP, Invasive BP, temperature, 12-lead ECG capability, multi-lead arrhythmia, and 12-lead ST analysis. The X2 must operate on battery power for at least 3 hours with basic monitoring configuration, must provide touchscreen and hard key input devices, and must have a 3-6" flat panel display.
- Must permit the addition of supplemental modules for additional parameters as necessary

#### • PACU. ED Monitors:

- Must meet all bedside monitor general requirements
- o Must have a color LCD display of at least 12"
- Must be an all-in-one display and processor; must not require an additional screen
- Must be capable of displaying at least 6 waveforms simultaneously
- o Must be configured for use in ICU settings
- PACU monitors must be compatible with the Philips X2 or equivalent for continuous monitoring post-surgery; must include battery extensions for transport with EtCO2
- ED monitors must be compatible with existing MMS and must provide at least 3 hours of battery operation for patient transport

# • ICU Monitors (MICU, SICU, CCU):

- Must meet all bedside monitor general requirements
- o Must have a color LCD display of at least 19"
- o Must be capable of displaying at least 8 waveforms simultaneously
- Must be configured for use in ICU settings

- Must include at least 8 slot FMS rack with MMS or X2 mount
- SICU monitors must be compatible with Philips X2 or equivalent for continuous monitoring post-surgery; must include battery extensions for transport with EtCO2
- o MICU and CCU monitors must be compatible with existing or new MMS.

#### Central Stations:

- o Hardware, software and licenses must be provided
- Full disclosure capabilities
  - 72 hours full disclosure
  - Potential for at least 7 days of graphic trend and display
  - Storage of alarm data
  - Event storage
- o Alarm review is required to satisfy TJC NCPG.06.01.01.
- o Arrhythmia histories
- O At least 3 levels of alarms with visual and audible alerts
- Must allow for remote view of any patient being monitored on the network
- Must be capable of displaying at least 32 patients on at least 24" touch screen displays
- Must provide sector minimization, manual and/or automatic resizing of sectors to ensure ease of visibility of high acuity patient data
- Must allow for remote patient management including admit, transfer, and discharge
- Must capture and store a log of alarms and events for at least 50 days, searchable by patient, unit, alert filters, or action filters. Log must be available for display or export into Excel without additional cost to the facility. Alarm logs will be used to address TJC NPSG.06.01.01 for clinical alarm systems.
- Must utilize centralized licensing to allow flexibility of moving licenses as future needs arise

## • Clients:

- A workstation able to view patients presently viewed on a central station, to provide 2 points of oversight over the same patients.
- o Must show all patient parameters, alarms, and waveforms.

## • Telemetry:

- Must be wearable patient monitors with built in measurements including SpO2 and ECG
- Must have a minimum 2.5" color touchscreen display with automatic screen locking
- o Must be capable of displaying real-time waveforms
- o Must withstand accidental water submersion per IPX7, IEC 60592
- Must support disposable batteries or single rechargeable lithium-ion battery
- O Lithium-ion battery must charge in less than 7 hours from 90% depletion

- o Telemetry monitor must provide at least 10 hours of continuous use in telemetry mode when networked and recording continuous ECG and SpO2
- o Telemetry monitor must weigh less than 12 oz with Lithium-ion battery
- Must connect to the central station via a wireless network; the central station must provide primary patient monitoring and alarm function
- Must record data locally when not connected to a wireless network, this data must be uploaded upon reconnection to the wireless network
- Must utilize a 1.4 GHz smart hopping network to prevent interference with existing wireless networks and equipment in the facility

## • Biomed Spares:

- At least one of each monitor and peripheral (MMS, FMS, X2) must be provided as spares for Biomedical Engineering.
- Spares must be configured identically to monitors used in clinical areas to ensure continuity of care in the event of equipment breakage.

### **TRAINING**

- Vendor must provide both clinical and biomedical service training
- Clinical training must take place at the facility, to include all shifts of impacted wards in the hospital. At least 5 standard and overtime shifts must be included.
- Biomedical training must include at least 3 technicians; if off site, all travel and lodging
  must be included. Additional technicians above the required minimum may be included
  pending available funding.
- Biomedical training must include: hardware and software training for physiological monitoring; hardware, software, and infrastructure training for telemetry
- Clinical training must be provided no more than three weeks prior to installation unless otherwise approved by the COR.
- Clinical training must include: initial training; go live support; super user training; and Computer Based Training if required.

#### GENERAL SPECIFICATIONS

- Turn-Key Installation providing all services, hardware, and accessories for a complete and functional system.
- The monitors will be networked together unless otherwise specified by the COR
- Minimal layers of Data entry to facilitate rapid acquisition of patient data
- All cables and accessories to provide a complete and functional system are included
- Must be able to interface seamlessly with the facility Clinicomp CIS and the PICIS ARK Information systems.
- Must provide continuity of monitoring of patients during the project to install new monitoring.
- Must have at least two (2) field service engineers within 1 hour of Richmond, Virginia.

## **NETWORK REQUIREMENTS**

The vendor will provide current and official MDS2 and 6550 forms regarding all the equipment they are providing as part of the monitoring installation. These forms must be received as part of the bid documentation unless otherwise approved by the COR and Contracting Officer.

The quote for the monitoring network installation shall be a separate line item and shall include cost per network node, including cable run, terminations, any necessary hardware and installation cost. Any infrastructure currently used for patient monitoring may be used, however any component that is not state-of-the-art must be updated to meet current market capabilities including any switches, servers, etc. All above ceiling cable runs shall be placed in available existing conduit or vendor-provided conduit, and properly routed through interstitial area per hospital facilities requirements. Cables shall be bundled neatly and in a professional manner especially when cables converge at network hardware. Cables shall be marked at each end indicating the termination point of the other end. Network cabling, terminations and any patch panels used shall be CAT-5E/CAT6 certified. The network shall be IPV6 compatible unless otherwise approved by the COR. The monitoring network may be a part of the VA network, but it will be segmented by VLANs. In the event of VA network downtime there shall be redundancy to allow the monitoring network to operate independently of the VA network. All networking hardware shall be wall or rack mounted in mutually agreed upon areas. The preferred placement of servers or additional computers would be in a centralized computer room. Any network hardware that cannot be located in the server room shall be placed in data closets or secure locations. Any wireless equipment shall be compatible with existing hospital wireless network, including being FIPS 140-2 encryption compliant and must be approved by the COR prior to installation.

All monitoring networking designs must be provided to and approved by the COR prior to starting the network installations.

Any cable run through plenum space shall be plenum rated according to NEC and applicable fire codes. ALL WALL PENETRATIONS SHALL BE SEALED ACCORDING TO ALL APPLICABLE CODES AND HOSPITAL POLICY with UL approved materials based on the type of wall/vertical structure they are penetrating. All sealing material must be approved prior to use by the COR.

The contractor will follow all Hunter Holmes McGuire VAMC construction safety policies as well as ICRA, fire-stopping, and permitting procedures. The contractor will provide their own HEPA filtered environmental containment to utilize per ICRA procedures to control the infection and dust risks to patients during the network, cabling, and hardware installation work when removing ceiling tiles, penetrating walls or ceilings, running cabling, in addition to the usual controlled by covering any doors, vents, and permanent equipment. INFECTION CONTROL POLICIES SHALL BE ADHERED TO AT ALL TIMES AND PERMITS APPROVED EACH DAY AND POSTED. Unit to unit connection charge shall include all cable runs, hubs, switches and any other hardware or software required. All cable runs shall be tested for full functionality and run length. Copper run lengths greater than 320' will not be accepted. The vendor shall provide a copy of the test results to the Hunter Holmes McGuire VAMC [REDACTED] in electronic format that can be displayed and/or viewed. Cable length shall be included in this report. Documentation of the vendor network shall also be provided and include a marked up drawing (as built) showing jacks and room locations. A spreadsheet and network diagram shall also be provided with the following information: switches, routers, servers, gateways, and WMTS access point locations (named in a convention agreeable to the facility). The interface will be compliant with VA National interface standard. Any offsite server or network maintenance or

support provided by the vendor can only be done via VPN access after the vendor has obtained the VPN access from the VA.

# CONTRACTOR'S RESPONSIBILITY IN CONNECTION WITH INSTALLATION

The price quoted shall include cost of installation which consists of assembling, positioning, and mounting of all equipment listed on the delivery order and connections of all cables. The equipment contractor is responsible for furnishing and pulling interconnecting wiring and cabling through conduit (either existing or provided by the contractor, as needed), and for making any connections. Interconnecting wiring and cabling which do not run through conduit shall be furnished and installed by the equipment contractor. It is the responsibility of the equipment contractor to install junction boxes, wall/ceiling mounts and support structures supplied by the equipment contractor. The equipment contractor must provide well qualified field engineers or technicians to install and conduct all necessary tests which shall begin within (10) ten days after receipt of notice to proceed from the Contracting Officers Representatives (COR).

Once installation is started, it shall be continuous, eight (8) hours per day coinciding with the regular working hours at the hospital. Compliance with this requirement shall be manifest by the continuous presence of the engineers or technicians on the job site during the daily working period. Installation shall be continuous, without interruption, until all installation and testing work has been completed. The contractor must provide the physical movement of the equipment from the storage point at final destination, to the area of installation, and the uncrating of the equipment. Overtime or off-hours installation will be expected to minimize impact to patient care in certain areas. Overtime or off-hours requirements are to be included at no additional cost to the Hunter Holmes McGuire VAMC.

Rigging and special handling costs, if required, to move the equipment from dock area to the installation site within the consignee's premises, shall be borne by the equipment contractor.

Upon receipt of notice to proceed with installation, it shall be the contractor's responsibility to inform the Contracting Officer of any problems which may be anticipated in connection with installation or which will affect optimum performance once installation is completed. Such matters as inadequacy of power supply, limitations of site or inadequate preparation of site shall be reported prior to start of installation. Installation shall not proceed under such circumstances until authorized by the Contracting Officer.

In the event that progress of the installation is interrupted through no fault of the contractor, the continuous installation referenced in the preceding paragraphs may be terminated until such time as the cause of delay has been eliminated, and then shall be resumed within twenty-four (24) hours after the contractor has been notified that work may again proceed. Such termination of continuous installation shall be made only after two (2) hour notice has been given to the Contracting Officers Representative (COR) or person acting in that capacity at the hospital receiving installation. Contractor must notify the Contracting Officer within 48 hours of termination of installation.

MAINTAINING MONITORING OF PATIENTS THROUGHOUT INSTALLATION AND REMOVING THE OLD HARDWIRED MONITORING SYSTEM.

- The contractor will install the new monitoring system without any patient monitoring downtime. If downtime is needed, then the contractor must submit this in their installation plan to the COR to be approved six weeks in advance of the work.
- During the installation of the new monitoring system, the contractor will ensure that they do not disconnect any networking or capability of the current Philips monitoring system.
- If the contractor needs to disconnect the Philips network or remove mounted Philips hardware, they will provide a replacement monitoring system for that room, area, ward that has the same parameters in order to prevent any downtime of patient monitoring.
- The contractor will remove the old Philips monitoring system from the halls and walls of the facility and inform the COR if there are any needs to patch and paint the walls or penetrations each day so they can be addressed by the facility.
- The facility will provide a place to collect, inventory and store the old Philips monitoring system during this project.

# LICENSING SOFTWARE REQUIREMENTS

The vendor shall provide all computer software, access keys or codes, or external devices required for the operation, calibration, or repair of the equipment purchased. Any such items not listed on the price quote and required for maintenance of the system, shall be taken as included with the purchase of the system. Any upgrades or changes to the maintenance software, hardware, or access keys or codes shall be provided at "no charge" to the medical center during the time the equipment is operational at this facility. All application software licenses are included in the purchase of the equipment and shall not a require renewal charge for the period of time the equipment is in use in the facility.

## **USER AND SERVICE MANUALS**

The vendor shall provide, at no charge, at least 3 complete and unabridged sets of operator manuals, service manuals, electronic schematics, troubleshooting guides and parts lists for each piece of equipment purchased for the medical center. These manuals will include all components and subassemblies, including those not manufactured by the vendor. These manuals and documentation shall be identical to the ones supplied to the manufacturer's service representatives and shall contain the diagnostic codes, commands, and passwords utilized in maintenance, repair and calibration of the equipment. The vendor shall disclose at the time of quoting of this equipment any post warranty charges such as remote service or application access charges, telephone technical or application support charges, or any fees associated with supporting this equipment including the hourly rate for onsite maintenance service, and the cost and description of the various maintenance coverage products.

## HARDWARE UPGRADES

(a) All equipment and related peripherals contracted for shall be state-of-the-art technology. "State-of-the-art" is defined as the most recently designed components that are announced for marketing purposes, available, maintained and supported in accordance with mandatory requirements specified in the solicitation. Components and products with a manufacturer's planned obsolescence within the first year of contract award are not acceptable.

- (b) If hardware upgrades become available after award of this contract but prior to installation of the equipment, the contractor is requested to offer them to the Contracting Officer for consideration.
- (c) The contractor's proposal for such upgrades shall include the following information:
  - (1) Pricing information, to include both the price of the equipment to be added and the equipment to be deleted.
  - (2) Specific awarded items that shall be changed if the proposal is awarded.
  - (3) Performance data, including both comparisons to the specification requirements and to the equipment on contract.
  - (4) A detailed description of the differences between the awarded items and those being proposed, and a specific analysis of the comparative advantages/disadvantages of the items involved.
  - (5) An evaluation of the effect proposed changes will have on the life cycle of the equipment and an associated cost impact as it relates to site preparation, installation, maintenance, and operational expense.
  - (6) An analysis of the timeframe required to institute the change.

# **5.1 Task 1 - Enterprise Management Controls.**

- 5.1.1 <u>Subtask 1 Integration Management Control Planning</u>. Provide the technical and functional activities at the required level for integration of all tasks specified within this SOW. Include productivity and management methods such as quality assurance, progress/status reporting and program reviews. Provide the centralized administrative, clerical, documentation and related functions.
- 5.1.2 <u>Subtask 2 Contract Management</u>. Prepare a Contract Management Plan describing the technical approach, organizational resources and management controls to be employed to meet the cost, performance and schedule requirements throughout Contract execution. Provide a monthly status report monitoring the quality assurance, progress/status reporting and program reviews applied to this contract.

Deliverables: Contract Management Plan Monthly Status Report

# 6. Performance Monitoring

Performance will be monitored by the Contracting Officer Representative, [REDACTED], or the [REDACTED], throughout the implementation of this project. Any deficiencies will be reported to the Contracting Officer.

# 7. Security Requirements

Vendor must provide a valid MDS2 and 6550 form with bid documentation. The C&A requirements do not apply and a Security Accreditation Package is not required.

# 8. Packaging, Packing and Shipping Instructions.

Vendor is responsible for delivery coordination as part of implementation project management.